

Collaborative Islet Transplant Registry (CITR)

www.citregistry.org

Description of Project

- The mission of the Collaborative Islet Transplant Registry (CITR) is to expedite progress and promote safety in islet/beta cell transplantation through the collection, analysis, and communication of comprehensive and current data on all islet/beta cell transplants performed in North America.
- CITR collects both retrospective and prospective data. All islet transplants performed since January 1, 1996 will be captured by the Registry, as well as islet transplants performed until September 2006.

Accomplishments for 2004

- First Annual Investigators' Meeting held November 16-17, 2003 in Miami, Florida.
- Collaboration with the National Center for Research Resource's Islet Cell Resource (ICR) Consortium coordinating center including data sharing and meeting participation.
- Data Sharing with United Network for Organ Sharing (UNOS) for CITR donor data.
- Fully implemented payment system for centers participating in CITR.
- Election and implementation of four CITR working Committees (Compliance, Data Monitoring, Publications/Presentations, and Transplant Coordinators/Data Managers).
- Conference Calls and face-to-face meetings for all four working Committees and the Executive Committee and Scientific Advisory Committee.
- Collaboration with the Juvenile Diabetes Research Foundation (JDRF) and discussion of adding five JDRF funded European sites to CITR.
- Collaboration with NIAID to allow for the participation of the Immune Tolerance Network's islet transplant protocol participants in CITR.
- Creation and review of the first Annual Report, to be published in June 2004.
- Fully executed public website and secured password protected website for Investigators and Committee members.
- Fully implemented data capture system, quality control measures and quality assurance reports.
- Drafted data collection elements for Xenotransplant component to CITR.
- Outline and information provided on information technology to develop a single islet database module that may be implemented at all islet transplant centers. Information sent to three centers for review.
- Data dictionaries and CITR data structures shared with software developer Hickman Kenyon for use in their software development for a single islet database module.
- Publications and Presentations made for CITR from November 2003 – April 30, 2004:

- *The Collaborative Islet Transplant Registry*, 2003 Rachmiel Levine Symposium, Presentation, November 7, 2003
- *The Collaborative Islet Transplant Registry*, 2003 Islet Summit Conference Series 2003, November 15, 2003
- Upcoming publications and presentations for CITR:
 - *The Collaborative Islet Transplant Registry*, American Transplant Congress, Poster Session, May 15-18, 2004
 - *The Collaborative Islet Transplant Registry*, American Diabetes Association, Poster Session, June 5-7, 2004
 - “The Collaborative Islet Transplant Registry” in *Transplantation of the Pancreas*, Publication, publication date TBA
 - “The Collaborative Islet Transplant Registry” in *Clinical Transplants 2003*, Publication, publication date TBA
 - “The Collaborative Islet Transplant Registry” in *Cell Biochemistry and Biophysics*, 2003 Rachmiel Levine Symposium Issue, Publication, publication date TBA
- Continue to recruit new islet transplant centers and assist them in the application process including IRB review and filing IND with FDA.
- Continue to hold web-conference training and refresher courses for new staff at existing centers.
- Meeting on June 4, 2004 at the American Diabetes Association on Metabolic Monitoring of Islet Transplantation recipients.

Future Directions

- Implement Xenotransplant component for CITR.
- Collect autograft data for CITR.
- Have five JDRF International Islet Transplant Centers participate in CITR.
- Further refine CITR and the islet transplant field in regards to metabolic monitoring of islet transplant recipients.
- Discuss adding a quality of life component to CITR.
- Develop and implement standards for reporting islet/beta cell transplants and their outcome.
- Collect and compile data on all islet/beta cell transplants in human recipients performed in North America and five JDRF European islet transplant centers.
- Increase the safety of islet/beta cell transplantation by electronically distributing the pertinent information of submitted adverse event reports to all participating clinical sites in a timely fashion.
- Perform scientific analysis on islet/beta cell transplant data, with particular emphasis on:
 - Safety of islet/beta cell transplant product and procedures, and protocol-regulated treatment products.

- Number of islet/beta cell transplants and retransplants performed, categorized by transplant institution, donor tissue source and handling, recipient category, transplant technique and site, and recipient treatment protocols.
- Efficacy of islet/beta cell transplants as defined by standardized outcome measures and as determined by donor factors, recipient demographics, donor-recipient matching, islet/beta cell processing and product characteristics, transplant technique and site, recipient treatment, and post-transplant events.
- Communicate comprehensive and current information on islet/beta cell transplantation to transplant centers, the diabetes and general health care community, and the interested general public via the CITR web site (<http://www.citregistry.org>), publications, and presentations.
- Stimulate prospective and retrospective studies on emerging issues of importance

CITR Materials to be Made Available to Researchers

- CITR Committee Agendas/Minutes and materials for discussion
 - Compliance
 - Data Monitoring
 - Publications/Presentations
 - Scientific Advisory Committee
 - Transplant Coordinators/Data Managers
- CITR Documents
 - Benefits for Joining CITR
 - Basic Slide Set on CITR for presentations
 - Protocol Template
 - User's Guide for Internet data entry
 - Request forms for analyses
 - Request forms for changes or additions to the Registry database
 - Manual of Procedures
 - Frequently Asked Questions and Answers
 - Case Report Forms
 - Sample participant brochures
 - Sample Follow-up Materials
 - National Cancer Institute's Common Terminology Criteria for Adverse Events
 - CITR Accrual Report
 - Data System Update Memos
 - Data Upload Instructions
 - Form Variable Names
 - Data Dictionaries
 - Codelists

Participants

Sponsor: National Institute of Diabetes and Digestive and Kidney Diseases

Coordinating Center:

The EMMES Corporation of Rockville, Maryland
University of Minnesota (subcontractor to The EMMES Corporation)

Scientific Advisory Committee (Voting members):

Chair:

Bernhard J. Hering, MD University of Minnesota

Members:

Reinhard G. Bretzel, MD, PhD	University of Giessen, Germany
Michael Cecka, PhD	University of California, LA
Mary D. Ellison, PhD, MSHA	United Network for Organ Sharing
Jerry P. Palmer, MD	University of Washington, Seattle
Camillo Ricordi, MD	University of Miami
A.M. James Shapiro, MD, Ph.D.	University of Alberta

Ad-hoc Scientific Advisory Committee Members:

Kim Badovinac	Canadian Organ Replacement Register (CORR); Canadian Institute for Health Information (CIHI)
Giacomo Basadonna, MD, PhD	University of Massachusetts
Nancy Bridges, MD	NIAID/NIH
Brian Flanagan, PhD	JDRF
Judith Fradkin, MD	NIDDK/NIH
Richard Knazek, MD	NCRR/NIH
Steve Phurrough, MD, MPA	Centers for Medicare & Medicaid Services
Laura St. Martin, MD, MPH	HRSA
Keith Wonnacott, MD	FDA/CBER

Participating Centers (in order of activation):

University of Minnesota*	Minneapolis, Minnesota
University of Miami, Diabetes Research Institute*	Miami, Florida
Baylor College of Medicine/ The Methodist Hospital	Houston, Texas
Southern California Islet Consortium – SCIC*	Duarte, California
University of Massachusetts Medical Center	Worcester, Massachusetts

Participating Centers *continued*

University of Tennessee, Memphis*	Memphis, Tennessee
Emory Transplant Center	Atlanta, Georgia
University of Pennsylvania*	Philadelphia, Pennsylvania
Northwestern University*	Chicago, Illinois
University of Chicago	Chicago, Illinois
Washington University, St. Louis*	St. Louis, Missouri
University of Alberta	Edmonton, Alberta, Canada
Center for Islet Transplantation at Harvard Medical School*	Boston, Massachusetts
Multiorgan Transplant Center	
University Health Network	Toronto, Ontario, Canada
University of British Columbia	Vancouver, British Columbia, Canada
Human Islet Transplantation in Seattle (HITS) Consortium*	Seattle, Washington
Laboratorio des Xenotrasplantes	Mexico City, DF, Mexico

* Denotes a center also participating in the National Center for Research Resources Islet Cell Resources Consortium (NCRRI/ICR).

Publications/Presentations Committee (2003-2004):

Chair:

Rodolfo Alejandro, MD University of Miami

Members:

Nancy Bridges, MD	NIAID
Tom Eggerman, MD, PhD	NIDDK
A. Osama Gaber, MD	University of Tennessee, Memphis
Elizabeth Holbrook, MT, ASCD	Emory University
Ali Naji, MD, PhD	University of Pennsylvania
R. Paul Robertson, MD	HITS
Craig Smith, MD	City of Hope/UCLA

Ad Hoc:

Bernhard Hering, MD University of Minnesota

Data Monitoring Committee (2003-2004):

Chair:

Marc Garfinkel, MD University of Chicago

Members:

David Baidal, MD	University of Miami
Bernhard Hering, MD	University of Minnesota
David Iklé, PhD	ICR Coordinating Center
Agnes Lo, BSP, PharmD	University of Tennessee, Memphis

Camillo Ricordi, MD
James Shapiro, MD, PhD

University of Miami
University of Alberta

Compliance Committee (2003-2004):

Members:

Shannon Inman
Fouad Kandeel, MD
Eileen M. Markmann, BSN
Peggy Murphy, RN, MS
David Radosevich, PhD

Baylor College of Medicine, Houston
City of Hope, California
University of Pennsylvania
University of Chicago
University of Minnesota

Transplant Coordinators/Data Managers Committee (2003-2004):

Chair:

David Baidal

University of Miami

Members:

Shelly Baker
Barbara Culbreath
Arthur Dea

University of Alberta
The University of Tennessee
Center for Islet Transplantation at Harvard
Medical School

Kathy Duderstadt
Cheryl Durkop

University of Minnesota
Baylor College of Medicine/
The Methodist Hospital

Celia Hartigan
Eileen Markmann
Peggy Murphy
Heather Robertson
Marti Sears
KD Shiang

University of Massachusetts
The University of Pennsylvania
University of Chicago
Washington University, St. Louis
Emory Transplant Center
Southern California Islet
Consortium (SCIC)

Elyse Stuart
Elizabeth Wright

Northwestern University
Multiorgan Transplant Center,
University Health Network

To be announced
To be announced

University of British Columbia
Human Islet Transplantation
in Seattle (HITS) Consortium

To be announced

Laboratorio des Xenotrasplantes